MAY 2 4 2001

510(k) Summary
for
OFI Biomedica SpA
Hemodialysis Tubing Sets

1. SPONSOR

OFI Biomedica S.p.A.
Via Libica 13
Trapani 91100
Italy

Contact Person: Franco Buffoni
Telephone: 011 39 45 8005555 - 591073

Date Prepared: June 27, 2000

2. DEVICE NAME

Proprietary Name:	Hemodialysis Tubing Sets
Common/Usual Name:	Hemodialysis System and Accessories
Classification Name:	Hemodialysis System and Accessories

3. PREDICATE DEVICES

Medisystems Dialysis Arterial-Venous Tubing Sets (K953823)
B. Braun Hemodialysis Blood Circuit (K952631).

4. DEVICE DESCRIPTION

The hemodialysis tubing sets are standard blood tubing sets for use with hemodialysis systems. The tubing sets are composed of various components such as tubing, luer locks, connectors, clamps, drip chambers, etc. that are configured for connecting a patient's vascular access system to a dialyzer. The tubing set components are pre-configured and packaged as an arterial line, a venous line, and an infusion line for various systems such as Fresenius, Baxter, Cobe, Althin, etc.

5. INTENDED USE

The Hemodialysis Tubing Sets are intended to transport blood from the patient's vascular access system to the hemodialyzer (arterial line) and from a hemodialyzer to the patient's vascular access system (venous line).

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The OFI Biomedical Hemodialysis Tubing and all of the predicate devices have the same intended use. They are all intended to transport blood from the patient's vascular access system to the hemodialyzer (arterial line) and from a hemodialyzer to the patient's vascular access system (venous line). Neither the OFI device nor predicate devices are intended for peritoneal dialysis. The OFI device and predicate devices are all indicated for patients receiving routine hemodialysis.

The OFI Biomedical Hemodialysis Tubing Set and the predicate devices are all composed of various sizes of tubing, connectors and clamps for connection to the arterial or venous access system

7. PERFORMANCE TESTING

The OFI Biomedica Biomedical Hemodialysis Tubing Set complies with AAMI/ANSI RD 17 Standard for Hemodialysis tubing sets. The OFI hemodialysis tubing sets have been tested to and passed biocompatibility testing according to ISO-10093.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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OFI Biomedica S.p.A.
c/o Cynthia J. M. Nolte, Ph.D., R.A.C.
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K001971
OFI Biomedica S.p.A. Hemodialysis Blood Tubing Sets
Dated: January 22, 2001
Received: February 28, 2001
Regulatory Class: II
21 CFR §876.5820/Procode: 78 FJK and FIB

Dear Dr. Nolte:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K001971

Device Name: OFI Biomedica S.p.A. Hemodialysis Tubing Sets

Indications For Use:

The OFI Biomedica Hemodialysis Tubing Sets, with transducer protector, are indicated for use in conjunction with hemodialysis systems and accessories. These sets are intended to transport blood from the patient's vascular access system to the hemodialyzer (arterial line) and from the hemodialyzer back to the patient's vascular access system (venous line). The sets may also include an infusion line. The compatibility of available configurations is the responsibility of the physician in charge.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K001971